SECTION 5: SUMMARY OF SAFETY AND EFFECTIVENESS (Revision July 9, 2008)

Premarket 510(K) Summary of Safety and Effectiveness

Submitter Information

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JUL 21 2008

Date Submitted: February 8, 2008

Device Name

Proprietary Name: ENDODRAPE™ Upper Endoscopy Drape
Common Name: non-sterile surgical/procedure drape
Classification Name: Surgical Drape and Drape Accessories
Regulation Number: 21 CFR 878.4370
Regulatory Class: II
Classification Code: KKX

Statement of Substantial Equivalence:

The Vortek Surgical ENDODRAPE™ Upper Endoscopy Drape is equivalent to ENDODRAPE™ Surgical and Diagnostic Procedure Drape used in colonoscopy.

Applicant Device	Predicate Device	Manufacturer	510(k) Predicate
ENDODRAPE™ Upper Endoscopy Drape	ENDODRAPE™ Surgical and Diagnostic Procedure Drape	Vortek Surgical, LLC	K070406

Description of Device: The Vortek Surgical ENDODRAPE™ Upper Endoscopy Drape is a single use, disposable covering intended for use in non-sterile surgical and diagnostic procedures. The ENDODRAPE™ Upper Endoscopy Drape consists of a non-woven surgical drape measuring 38" x 54" (97cm X 137cm), similar to other surgical drapes currently being marketed. As with the predicate colonoscopy drape, the ENDODRAPE™ Upper Endoscopy Drape is intended to protect patients, staff, and equipment from bodily secretions present during non sterile endoscopic procedures, with the only variation in size and configuration to provide optimal protection for upper gastrointestinal endoscopic procedures. The ENDODRAPE™ Upper Endoscopy Drape consist of materials commonly used for medical drape manufacturing including commercially available non-woven surgical drape fabric, Krayton, Velcro, LDPE, medical grade tapes, SMS, medical grade adhesives, hot melt, cold glue. The drape is intended for non-sterile use by the end-user and is supplied in individual heat sealed polybags.

Vortek Surgical, LLC
510(k) Number K080341
ENDODRAPE™ Upper Endoscopy Drape

Indications for Use: The intended use of the ENDODRAPE™ Upper Endoscopy Drape is to protect patients, staff and equipment from bodily secretions and to maintain a cleaner procedural site during non-sterile upper gastrointestinal endoscopic procedures. The device is a single use disposable drape that is provided non-sterile. The device can, however, be EtO (ethylene oxide) sterilized by the end user prior to use.

Technological Characteristics: The proposed ENDODRAPE™ Upper Endoscopy Drape has the same technological and design characteristics as the predicate device.

PHYSICAL PROPERTIES			
Property	**Test Standard**	**Comparison to Predicate**	**Submission Section**
Weight	ASTM D3776	Identical	18
Grab Tensile Strength	ASTM D5034	Identical	18
Water Impact	INDA IST 80.3	Identical	18
Water Hydrostatic	INDA IST 80.4	Identical	18
Surface Wetting Spray	INDA IST 80.1 (range 0-100)	Identical	18
Alcohol Repellency	INDA IST 80.6 (range 0-10)	Identical	18
Flame Retardency rated Class I, Normal Flammability	16 CFR Part 1610.4	Identical	18
BIOCOMPATIBILITY PROPERTIES			
Property	**Test Standard**	**Comparison to Predicate**	**Submission Section**
Cytotoxicity (MEM Elution)	ISO 10993-1:2003	Identical	15
Skin Irritation	ISO 10993-1:2003	Identical	15
Skin Sensitivity	ISO 10993-1:2003	Identical	15
AAMI LIQUID BARRIER CLASSIFICATION PROPERTIES			
Level	**Test Standard**	**Comparison to Predicate**	**Submission Section**
2	AAMI PB 70:2003 approved 23 October 2003 as an American National Standard	Identical	18

Non-Clinical Performance (Bench Testing): Non-clinical performance (bench) testing of the ENDODRAPE™ Upper Endoscopy Drape consisted of Physical, Mechanical, Liquid Barrier Penetration and Biocompatibility, in accordance with applicable industry recognized test methods. The ENDODRAPE™ Upper Endoscopy Drape were found to be acceptable for its intended use and identical to the predicate device.

Vortek Surgical, LLC
510(k) Number K080341
ENDODRAPE™ Upper Endoscopy Drape

Summary: The Vortek Surgical ENDODRAPE™ Upper Endoscopy Drape subject to this submission have the same intended use, non-clinical performance data, and technological characteristics as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas E. Szymczak
President
Vortek Surgical, LLC
1426 West 29th Street, Suite 300
Indianapolis, Indiana 46208

JUL 21 2008

Re: K080341
Trade/Device Name: ENDODRAPE™ Upper Endoscopy Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: Class II
Product Code: KKX
Dated: August 20, 2007
Received: June 24, 2008

Dear Mr. Szymczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-*0115*. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Vortek Surgical, LLC
510(k) Number K080341
ENDODRAPE™ Upper Endoscopy Drape

Indications for Use

510(k) Number (if Known): K080341

Device Name: ENDODRAPE™ Upper Endoscopy Drape (Model # 69052)

Indications for Use: The intended use of the ENDODRAPE™ Upper Endoscopy Drape is to protect patients, staff and equipment from bodily secretions and to maintain a cleaner procedural site during non-sterile upper gastrointestinal endoscopic procedures. The device is a single use disposable drape that is provided non-sterile. The device can, however, be EtO (ethylene oxide) sterilized by the end user prior to use.

Prescription Use_____ AND/OR Over-The-Counter Use:__X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shanil P. Murphy D.D.S.
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080341